PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION OF Moriarty, R.M.; Penmasta, R.; Guo, L.; Rao, M.S.; and Mehta, R.G.	)	
SERIAL NO.: 09/008,957	)	Group No. 1616
FILED: Jan. 20, 1998	)	Examiner: Badio
TITLE: 1α-HYDROXYVITAMIN D_5, ITS SYNTHESIS AND USE IN CANCER PREVENTION AND THERAPY	)	

DECLARATION UNDER 37 CFR § 1.132

I, John E. Nelson, declare as follows:

1. I am a citizen of the United States residing at 519 North Spring Avenue, LaGrange Park, Illinois 60526-5539.

2. I am a graduate of the University of Illinois, receiving a B.S. degree in 1975, an M.S. in 1976 and a Ph.D. degree in 1981 in Chemistry. In 1983 I received a Doctor of Medicine degree from Rush Medical College in Chicago, Illinois. I served my residency in Internal Medicine from 1983-1986 at Loyola University Medical Center in Maywood, Illinois. I received a Fellowship in Clinical Pharmacology from Northwestern University Medical Center in Chicago, serving there from 1986-87.

3. From 1988-1994 I served as Assistant Professor of Medicine and attending physician on teaching and patient care services at Loyola University Medical Center. From 1994-1997 I was Clinical Pharmacologist with Eli Lilly and Co., with primary responsibility for the Raloxifene (Evista) NDA clinical pharmacology support plan and studies. Raloxifene is now a major

drug used for the treatment of postmenopausal osteoporosis, and is under clinical evaluation for prevention of breast cancer.

4. I am currently a clinical pharmacologist overseeing Phase I-IV clinical development plans for new drug candidates, including overall plan development, timeline, budget, headcount, study sequence and placement. I am a reviewer of the journal Clinical Pharmacology and Therapeutics and the Journal of Clinical Pharmacology. I am author or coauthor of numerous articles in the field of clinical pharmacology and drug therapeutics.

5. I am familiar with the above identified patent application entitled "1α-hydroxyvitamin D_5, Its Synthesis and Use in Cancer Prevention and Therapy" and the office action dated February 8, 1999.

6. In my opinion Applicants' 1α-hydroxyvitamin D_5 compound exhibits surprising properties that would not have been expected at the time the compound was first synthesized by Applicants. Based on its structural similarity to other Vitamin D compounds, one skilled in the art of clinical pharmacology would have expected 1α-hydroxyvitamin D_5 to exhibit high calcemia. Instead, in tests performed on rats, 1α-hydroxyvitamin D_5 has exhibited relatively low calcemia while at the same time showing promise for use in the prevention of mammary tumorigenesis. I am aware of nothing in the literature that would have suggested that 1α-hydroxyvitamin D_5 would be useful in such an application. It is

my belief that Applicants were the first to synthesize 1α-hydroxyvitamin D_5 and the first to propose its use in cancer prevention and therapy.

7. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of any patent that may issue from the above-identified U.S. patent application.

John E. Nelson, M.D., Ph.D.

July 2, 1999
Date